IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 4041
Mi *et al.*	Art Unit: 1656
Appl. No.: 10/553,685 *(U.S. National Phase of Int'l. Appl. PCT/US2004/008323)*	Examiner: Carlson, Karen C.
§ 371 Date: November 1, 2006	Atty. Docket: 2159.0440003/EJH/CLD
For: **Nogo Receptor Binding Protein**	

Reply to Unity of Invention Objection

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated October 1, 2007, requesting an election of one group of claims to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group I, represented by pending claims 58-78, 80, 81 and 100. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

Additionally, the Examiner has required that Applicants elect a single variant of SEQ ID NO:2 or provide a single sequence or subsequence that will represent a subset of, or all of the variants of SEQ ID NO:2. Applicants hereby provisionally elect amino acids 454-458 SEQ ID NO: 2 as recited in claim 59, part (p). Amino acids 454-458 of SEQ ID NO:2 as recited in part (p) of claim 59 represent a subset of the sequences listed in parts (a), (d), (e), (f), (g), (h), (i), (k), (l), (o) and (q) of claim 59. Claims 58-78, 80-81 and 100 read in part on such sequences. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

These elections are made **with** traverse.

Applicants respectfully assert that division of the present claims is improper under PCT Rules 13.1 and 13.2. At page 2 of the Office Action, the Examiner contends that the claims in Groups 1-8 do not relate to a single inventive concept under PCT Rule 13.1 because they lack the same or corresponding technical features as required under PCT Rule 13.2. Specifically, the Examiner states that "Claim 58, for example, reads on a single amino acid, for example. Therefore, the inventions lack a special technical feature" (Office Action at p. 2). Applicants respectfully traverse these contentions.

First, Applicants wish to point out that claim 58 does not read on a single amino acid. The claim explicitly recites the term "polypeptide," which by definition requires more than a single amino acid. In addition, the claim requires that the polypeptide "is capable of decreasing inhibition of axonal growth of a central nervous system neuron." Such polypeptides are described, for example, in the specification on page 3, lines 3-24 and on page 12, lines 1-10. A single amino acid would not be expected to decrease inhibition of axonal growth of a central nervous system neuron.

Furthermore, under PCT Rule 13.2, an alleged group of inventions claimed in a single application fulfill the unity of invention requirement of PCT Rule 13.1 when they share one or more of the same or corresponding special technical features. The phrase "special technical features," means "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." PCT Rule 13.2. Applicants respectfully assert that the claims in first appearing invention (Group I) satisfy the unity of invention requirement, since they share a common technical feature -- the polypeptide is a fragment or variant of SEQ ID NO:2 and is

capable of decreasing inhibition of axonal growth of a central nervous system neuron -- that is a contribution over the prior art.

Additionally, the U.S. Patent and Trademark Office regulations provide guidance to Examiners in regard to unity of invention:

> (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combination of categories: . . .
>
> (2) A product and process of use of said product; . . . .

37 C.F.R. § 1.475(b)(2).

Here, Groups 1 and 6 possess unity of invention because all of their respective claims contain reference to the special technical feature, *i.e.*, a polypeptide fragment or variant of SEQ ID NO:2 that is capable of decreasing inhibition of axonal growth of a central nervous system neuron, a required limitation, and these claims represent a product and a use of said product. Thus, Groups 1 and 6 should be examined together.

Furthermore, Applicants respectfully traverse the Examiner's division of claims into eight groups and the reasons stated therefore for additional reasons. For example, Groups 1 and 2 are related as between polynucleotides and compositions comprising the polynucleotides and methods of treatment using the polynucleotides. Groups 1 and 3 are related as between polynucleotides encoding particular polypeptides and antibodies that bind the polypeptides. Groups 3 and 5 are related as between antibodies and methods of inhibiting signal transduction comprising contacting a cell with the antibodies. Groups 3 and 7 are related as between antibodies and methods of treatment comprising

administering the antibodies. Groups 1 and 4 are related as between polynucleotides encoding polypeptides and methods of inhibiting signal transduction comprising contacting a cell with the polypeptides. Groups 1 and 6 are related as between polynucleotides encoding polypeptides and methods of treatment comprising administering the polypeptides. Groups 1 and 8 are related as between polynucleotides and interfering RNA molecules that regulate expression of the polynucleotides.

Even assuming, *arguendo*, that Groups 1-8 represent distinct or independent inventions, Applicants submit that to search and examine the subject matter of these Groups together would not be a serious burden on the Examiner because publications that disclose polynucleotides and the polypeptides encoded by them often also disclose antibodies that bind to the polypeptides. Furthermore, a search for publications that disclose antibodies would lead the Examiner to publications that disclose methods of using the antibodies. Similarly, a search for publications that disclose polynucleotides that encode particular polypeptides would lead the Examiner to publications that disclose methods of using the polypeptides. In addition, a search for publications that disclose polynucleotides would lead the Examiner to publications that disclose interfering RNA molecules that regulate expression of the polynucleotides.

The M.P.E.P. §803 (Eighth Edition, Rev. August, 2001) states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of the M.P.E.P. §803, Applicants respectfully request that all claims be searched and examined in the subject application. Therefore, reconsideration and

withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

Furthermore, out of the utmost caution, Applicants respectfully request that, upon reaching allowable subject matter of a product claim, the non-elected process claims be considered for rejoinder.

In the Office Action at page 2, the Examiner states that there are 20 different "variants" of SEQ ID NO:2 listed in claim 59 and that "the variants differ in structure and cannot be searched via a single polypeptide or nucleic acid sequence search." With respect to the Examiner's requirement for an election of one sequence and the reasons stated therefore, Applicants respectfully traverse.

First, amino acids 454-458 of SEQ ID NO:2 as recited in part (p) of claim 59 represent a subset of the sequences listed in parts (a), (d), (e), (f), (g), (h), (i), (k), (l), (o) and (q) of claim 59. Thus, since the sequence of part (p) is a subset, and not a variant, of the sequences listed in parts (a), (d), (e), (f), (g), (h), (i), (k), (l), (o) (q), each of these sequences should be examined together with the sequence listed in part (p) of claim 59.

Furthermore, the sequences listed in sections (a) to (q) of claim 59 are each fragments of the Sp35 polypeptide sequence SEQ ID NO:2. (*See* specification, p.10, Table 1). Nucleotide sequences encoding the same protein are considered to satisfy the

unity of invention standard and will continue to be examined together. *See* MPEP § 1850.

Here, these sequences listed in sections (a) to (q) of the claim 59 possess unity of invention because all of them contain reference to the special technical feature, *i.e.*, an Sp35 polypeptide or a fragment or fusion polypeptide thereof that is capable of decreasing inhibition of axonal growth of a central nervous system neuron, a required limitation, that is a contribution over the prior art. Thus, a polypeptide of Sp35 or a fragment or fusion polypeptide thereof should be examined together.

Even assuming, *arguendo*, that the sequences listed in claim 59 lack unity of invention, Applicants are entitled to have at least ten sequences searched in the present application. The U.S. Patent and Trademark Office has implemented the following policy with respect to Unity of Invention concerning sequences:

> The USPTO has decided *sua sponte* to partially waive 37 CFR 1.475 and 1.499 *et seq.* to permit applicants to claim up to ten (10) nucleotide sequences that do not have the same or corresponding special technical feature without the payment of an additional fee.

See MPEP § 1850. Therefore, Applicants are entitled to have at least ten sequences searched in the present application without division.

In addition, even where patentably distinct inventions appear in a single application, restriction remains improper unless the Examiner can show that the search and examination of the groups would entail a "serious burden." See MPEP § 803. In the present situation, the Examiner has failed to make such a showing.

Applicants reserves the right to have additional species considered in the event that a generic claim is found to be allowable in accordance with 37 C.F.R. § 1.141(a).

Reconsideration and withdrawal of the Election of an Invention Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

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1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
737383_1.DOC